
कोविड-19 में इस्तेमाल के लिये
आईसीयू वेंटीलेटर — विशिष्टि

ICU Ventilators for use in
COVID-19 — Specification

ICS 11.040.10

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approved by the Medical Equipment and Hospital Planning Division Council.

This standard is based on essential feature of ventilators as identified by the Technical Committee of Directorate General of Health Services (DGHS) for procurement by HLL Lifecare Limited for COVID-19. This standard has been developed only as interim arrangement, as an emergency temporary measure in larger public interest, to cater to the present crisis due to COVID-19 and is intended to be used till further modification in this standard/migration to the existing Indian Standards on ventilators.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

ICU VENTILATORS FOR USE IN COVID-19 — SPECIFICATION

1 SCOPE

This standard specifies the minimum requirements and test methods for ICU ventilators to be used for COVID-19 patients requiring ventilation support.

2 REFERENCES

The standards listed below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below:

<i>IS No.</i>	<i>Title</i>
IS 13450 (Part 1) : 2018/ IEC 60601-1 : 2012 (Ed 3.1)	Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (<i>second revision</i>)
IS 13450 (Part 1/ Sec 2) : 2018/ IEC 60601-1-2 : 2014	Medical electrical equipment: Part 1 General requirements for the basic safety and essential performance — Section 2 Collateral standard: Electromagnetic disturbances — Requirements and tests
IS/ISO 80601-2-12 : 2011	Medical electrical equipment: Part 2-12 Particular requirements for basic safety and essential performance of critical care ventilators
ISO 19223 : 2019	Lung ventilators and related equipment — Vocabulary and semantics

3 TERMS AND DEFINITIONS

For the purpose of this standard, the definitions given in ISO 19223 : 2019 and the following shall apply:

3.1 Pressure Regulated Volume Controlled (PRVC) — mode of ventilator where a set tidal volume is delivered to the patient while maintaining the lowest pressure possible in the airway, to avoid trauma.

4 GENERAL REQUIREMENTS

4.1 General Requirements for Basic Safety and Essential Performance

The ventilator shall be compliant to IS 13450 (Part 1).

4.2 The ventilator shall be suitable for use in ICU for adults and pediatric patients.

4.3 The ventilator shall be microprocessor based with active exhalation valve.

4.4 The ventilator shall be turbine/compressor/bellow based and shall be operable on both central oxygen lines and air supply source.

5 FUNCTIONAL REQUIREMENTS

5.1 Modes of Ventilation

The ventilator shall have both invasive and non-invasive features. The ventilator shall be able to function in the following modes:

- a) Pressure controlled — Continuous Mandatory Ventilation (PC-CMV)
- b) Pressure Controlled — Synchronized Intermittent Mandatory Ventilation (PC- SIMV)
- c) Volume Controlled — Synchronized Intermittent Mandatory Ventilation (VC- SIMV)
- d) Volume controlled — Continuous Mandatory Ventilation (VC-CMV)
- e) Assist/Control Ventilation (ACV)
- f) Continuous Positive Airway Pressure (CPAP)
- g) Bi-level Positive Airway Pressure (BIPAP)²⁾

NOTE:

1 Pressure support ventilation mode available can be used in place of CPAP and BIPAP.

2 Airway pressure release ventilation (APRV), Pressure Regulated Volume Controlled (PRVC), Bi-phasic and auto-weaning modes are desirable.

5.2 Calibration

The ventilator shall undergo automatic calibration on start-up.

5.3 Peak Pressure

The ventilator shall have peak pressure of 60 cmH₂O.

5.4 Peak Respiratory Rate

The ventilator shall have peak respiratory rate of 40 breaths per minute.

5.5 Inspiratory Time

The ventilator shall have inspiratory time at least in the range of 0.3-2.5 s.

5.6 Tidal Volume

The ventilator shall have tidal volume in the range of 50-600 ml.

5.7 Peak Flow Rate

The ventilator shall have peak flow rate of at least 120 litre/minute (± 10 percent).

5.8 PEEP

The ventilator shall have PEEP value of 0 cmH₂O to 30 cmH₂O (in increments of 1 cmH₂O).

5.9 Pressure Support

The ventilator shall have the pressure support in the range of 5-40 cmH₂O.

5.10 FiO₂ Delivery

5.10.1 The FiO₂ delivery of the ventilator shall be independent of the flow rate PEEP and the minute volume.

5.10.2 The FiO₂ delivery of the ventilator shall be adjustable between 21 to 100 percent.

5.10.3 *Inspiratory: Expiratory Ratio (I : E ratio)*

The ventilator shall have the I:E ratio in the range of 1:4 to 4:1.

5.11 Trigger Flow Sensitivity

The ventilator shall have trigger flow sensitivity in the range of at least 1 litre/min. to 10 litre/min.

5.12 Volume Accuracy

The ventilator shall have volume accuracy up to 10-15 percent of total tidal volume supported by the machine.

5.13 The ventilator shall have provision for leak volume compensation.

5.14 The ventilator shall have provision for inspiratory pause.

5.15 Monitoring of parameters

5.15.1 The ventilators shall have provisions for monitoring of following parameters:

- a) Respiratory phase and type,
- b) Exhaled tidal and minute volume,
- c) Respiratory rate,

- d) Total leak percentage/Leak volume,
- e) Spontaneous minute volume,
- f) Inspiratory: Expiratory ratio (I : E Ratio),
- g) Peak inspiratory and end expiratory pressure,
- h) Mean and plateau pressure, and
- i) Auto/intrinsic PEEP.

5.15.2 The ventilator may have provisions for monitoring of following parameters (optional):

- a) Rapid shallow breathing index (RSBI),
- b) Static compliance and resistance,
- c) Low inflection point (LIP) and upper inflection point (UIP),
- d) Maximum inspiratory pressure, and
- e) Lung recruitment maneuver and monitoring.

5.16 Graphics

5.16.1 The ventilator shall be equipped with a display screen of size not less than 6.5 inches.

5.16.2 The ventilator shall have graphics mode with display of the following scalars:

- a) Flow versus time,
- b) Pressure versus time, and
- c) Volume versus time.

5.16.3 The ventilator may have display of the following loops (optional) :

- a) Flow/Volume,
- b) Pressure/Volume, and
- c) Pressure/Flow.

5.17 Alarms

5.17.1 The ventilator shall be equipped with an alarm system that shall sound alarm at following fault conditions:

- a) Power disconnected** — The alarm shall trigger when the main power chord gets unplugged.
- b) Patient disconnected** — The alarm shall trigger when $PIP < (\text{Desired Pressure} \times 0.6)$.
- c) High inspiratory pressure** — The alarm shall trigger when $PIP < (\text{Desired Pressure} \times 0.6)$
- d) High PEEP** — The alarm shall trigger when $PEEP > \text{Set PEEP} + 2$ or 6 Consecutive cycles
- e) High respiratory rate** — The alarm shall trigger when $RR > 70$.
- f) Power sensor failure** — The alarm shall trigger when power sensor fails to respond.
- g) Read/write error (if applicable)** — The alarm shall trigger when settings saved in memory could not be read.

h) Ventilator temperature error — The alarm shall trigger when the core temperature of ventilator CPU exceeds 85°C.

i) System failure (Safe mode) — The alarm shall trigger when vital components become inactive.

j) Low tidal volume — The alarm shall trigger when tidal volume becomes lower than Set Tidal Volume $\times 0.75$ for six continuous cycles.

5.17.2 The ventilator shall have provision of maintaining an alarm history.

5.18 Battery backup — The ventilator shall have inbuilt rechargeable battery backup of at least one and half hours (± 10 percent).

5.19 Programmable Electrical Medical Systems

The ventilator shall conform to the requirements given in the 14 of IS 13450(Part 1).

6 TEST METHODS

6.1 Tests for General Requirements for Basic Safety and Essential Performance

The following tests shall be carried out for checking compliance of the ventilator for basic safety and essential performance as per IS 13450(Part 1):

<i>Sl. No.</i>	<i>Test Description</i>	<i>Method of Test, Refer to Clause</i>
1	Power input	4.11
2	Humidity preconditioning treatment	5.7
3	Determination of accessible parts	5.9.2
4	Durability and legibility of marking	7.1.2 and 7.1.3
5	Accessible parts including applied parts	8.4.2 d)
6	Residual voltage in attachment plug	8.4.3
7	Residual voltage or energy in capacitors	8.4.4
8	Patient leads	8.5.2.3
9	Working voltage measurements	8.5.4
10	Defibrillation proof — Applied part — Measurements of hazardous electrical energies	8.5.5.1 a)
11	Defibrillation proof — Applied part — Verification of recovery time	8.5.5.1 b)
12	Defibrillation proof — Applied part —Energy reduction test	8.5.5.2
13	Impedance and current -carrying capability of protective earth connections	8.6.4
14	Earth leakage current	8.7.4.5
15	Touch current	8.7.4.6
16	Patient leakage current	8.7.4.7 and 8.7.4.9
17	Patient leakage current with mains on F-Type applied part	8.7.4.7 b)
18	Patient auxiliary current	8.7.4.8
19	Measurements of thickness of solid insulation	8.8.2
20	Dielectric strength	8.8.3
21	Ball pressure	8.8.4.1
22	Resistance to environmental stress	8.8.4.2
23	Application — Short circuiting of one side of insulation in the mains parts between parts of opposite polarity.	8.9.2
24	Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts.	8.9.3.2
25	Thermal cycling tests on one sample of cemented joint with other insulating parts.	8.9.3.3
26	Creepage distance and air clearances	8.9.4
27	Cord anchorage	8.11.3.5
28	Cord bending	8.11.3.6
29	Arrangement of mains terminal devices	8.11.4.2 e)
30	Access to hazardous moving parts	9.2.1
31	Gaps	9.2.2.2
32	Overtravel end stops	9.2.3.2
33	Sharp edges	9.3
34	Instability — Overbalance in transport position	9.4.2.1

<i>Sl. No.</i>	<i>Test Description</i>	<i>Method of Test, Refer to Clause</i>	<i>Sl. No.</i>	<i>Test Description</i>	<i>Method of Test, Refer to Clause</i>
35	Instability — Overbalance excluding transport position	9.4.2.2	60	Ingress of water or particular matter	11.6.5
36	Instability — Overbalance from horizontal and vertical forces	9.4.2.3	61	Cleaning and disinfection	11.6.6
37	Castors and wheels — Force for propulsion	9.4.2.4.2	62	Sterilization	11.6.7
38	Castors and wheels — Movements over a threshold	9.4.2.4.3	63	Interruption of power supply	11.8
39	Instability from unwanted lateral movement (including sliding) in transport position.	9.4.3.1	64	Limited power circuit	13.1.2
40	Instability from unwanted lateral movement (including sliding) excluding transport position.	9.4.3.2	65	Electrical single fault condition	13.2.2
41	Handle loading	9.4.4 c)	66	Failure of thermostats	13.2.4
42	Cathode ray tube	9.5.2	67	Failure of temperature limiting devices	13.2.5
43	Sound pressure level measurements	9.6.2.1	68	Impairment of cooling	13.2.7
44	Hand — Transmitted vibration	9.6.3	69	Locking of moving parts	13.2.8
45	Hydrostatic pressure	9.7.5	70	Interruption or short circuit of motor capacitors	13.2.9
46	Support system	9.8.1 and 9.8.2	71	Heating element overload	13.2.13.2
47	Safety catch evaluation	9.8.1 and 9.8.2	72	Motor running overload	13.2.13.3
48	Static forces due to loading from persons	9.8.3.2	73	Push test	15.3.2
49	Dynamic forces due to loading from persons	9.8.3.3	74	Impact	15.3.3
50	X-radiation (Ionizing radiation)	10.1	75	Drop impact	15.3.4
51	Microwave radiation	10.3	76	Rough handling	15.3.5
52	Laser	10.4	77	Mould stress relief	15.3.6
53	Normal heating	11.1	78	Excessive current and voltage protection	15.4.3.5
54	Temperature measurements — Change of resistance method	11.1.3 d)	79	Actuating parts of controls (Knob pull and limitations of movements)	15.4.6.1 and 15.4.6.2
55	Identification of source of ignition	11.2.2.1	80	Loading test of foot-operated control device	15.4.7.1 b)
56	Construction requirements for fire enclosure of ME equipment	11.3	81	Accidental operations of ME equipment	15.4.7.1 c)
57	Overflow	11.6.2	82	Transformers short — circuit test	15.5.1.2
58	Spillage	11.6.3	83	Transformers over load — circuit test	15.5.1.3
59	Leakage	11.6.4 and 13.2.6	84	Transformers dielectric — strength	15.5.2
			85	Touch current	16.6.1
			86	Earth leakage current of multiple socket outlet	16.6.2
			87	Patient leakage current	16.6.3

6.2 Tests for Electromagnetic Compatibility

The following tests shall be carried out for checking compliance of the ventilator for electromagnetic compatibility as per IS 13450 (Part 1/Sec 2):

<i>Sl No.</i>	<i>Test Description</i>	<i>Recommended Standard to be followed as per IS 13450 (Part 1/Sec 2)</i>
i)	Harmonics on AC mains	IEC 61000-3-2
ii)	Voltage Fluctuation/ Flicker	IEC 61000-3-3
iii)	Conducted Emission	CISPR 11/EN 55011
iv)	Radiated Emission	CISPR 11/EN 55011
v)	Voltage dips and interruption	IEC 61000-4-11
vi)	Conducted RF	IEC 61000-4-6
vii)	Radiated RF	IEC 61000-4-3
viii)	Power frequency magnetic field	IEC 61000-4-8
ix)	Surge	IEC 61000-4-5
x)	Electrical fast transient/burst	IEC 61000-4-4
xi)	Electrostatic Discharge (ESD)	IEC 61000-4-2

6.3 Tests for Functional requirements

The following tests shall be carried out for checking compliance of the ventilator for functional

requirements as per IS/ISO 80601-2-12:

<i>Sl No.</i>	<i>Test Description</i>	<i>Method of Test, Refer to Clause</i>
i)	Volume-control inflation-type testing	201.12.1.101
ii)	Pressure-control inflation-type testing	201.12.1.102
iii)	Other inflation types testing	201.12.1.103
iv)	Inspiratory volume monitoring	201.12.1.104
v)	O ₂ concentration change test	201.12.1.105

6.4 Test for Sounds/Alarms

Refer Sl. No. 43 of 6.1 and 65dB alarm by dB meter in an associated environment.

7 PACKAGING

The packing shall be done as agreed to between the purchaser and the manufacturer/supplier. The manufacturer/supplier shall also provide instruction manual for safe operation of the ICU ventilator for use in COVID-19.

8 BIS CERTIFICATION MARKING

The ventilator may also be marked with the Standard Mark. The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations made thereunder. The details of the conditions under which the license for the use of the Standard Mark may be granted to manufacture or producers may be obtained from the Bureau of Indian Standards.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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